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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,431	06/05/2001	Karl Kolter	51497	5147

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/873,431	KOLTER ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12,13,16-23,25 and 27-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12,13,16-23, 25 and 27-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for reconsideration and a listing of all the claims filed 5/11/06. No claim is amended in the filing of 5/11/06. Claims 1-9, 12, 13, 16-23, 25 and 27-33 are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-9, 12, 13, 16-23, 25 and 27-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no description of what "finely dispersed" is and there is no description of how polyvinylpyrrolidone is "finely dispersed" in the polyvinyl acetate.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-7, 9, 12, 13, 16-23, 25 and 27-33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ortega (US 4,837,032).

Ortega discloses compressed tablet comprising theophylline, polyvinylpyrrolidone, polyvinyl acetate, cellulose acetate phthalate and a mixture or stearic acid, magnesium stearate and talc (abstract; column 2, lines 56-68,. column 3, lines 57-63., and column 4, lines 3-18). The theophylline granule composition is wet granulated from a mixture heated to 40 °C to 50 °C (example 1), which is dried before combining with the mixture of polyvinylpyrrolidone and polyvinyl acetate and lubricant. Stearic acid is listed as an additive in the instant application (page 8, line 20) and the stearic acid of Ortega meets the limitation of additive recited in instant claim 25. Regarding claim 17, which is drawn to composition, it is noted that how the composition is made carries no patentable weight because product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps; and "[e]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does

not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Ortega discloses a process of wet granulating a mixture of theophylline, polyvinylpyrrolidone cellulose acetate phthalate; the dried granulate is then combined with mixture of polyvinylpyrrolidone, polyvinyl acetate and lubricant, which is a mixture or stearic acid, magnesium stearate and talc (abstract; column 2, lines 56-68; column 3, lines 57-63; and column 4, lines 3-18) at a temperature of 40 °C to 50 °C (example 1). Regarding the molecular weight of the polyvinylpyrrolidone recited in instant claim 1, it is noted from the silence of Ortega on the molecular weight of the polyvinylpyrrolidone, that polyvinylpyrrolidone of any molecular weight can be used except declared by applicants to be contrary to Ortega's invention. Regarding the ratio of polyvinyl acetate to polyvinylpyrrolidone, it is within the purview of the person of ordinary skill or skill in the art to determine the relative amounts of the polyvinylpyrrolidone and polyvinyl acetate necessary for a sustained or controlled release formulation and in this case however, in example I, Ortega uses 9 kg of polyvinyl acetate in particle form to 6 kg of polyvinylpyrrolidone which translates into 60 :40 or 6:4 (9/15 to 6/15); the 60:40 polyvinyl acetate :polyvinylpyrrolidone meets the limitation of claim 2. Ortega teaches a sustained release composition comprising theophylline, polyvinyl acetate and polyvinylpyrrolidone, cellulose acetate phthalate and optionally lubricant (abstract). Ortega specifically teaches that water-soluble polymers or gel forming polymers are used in the composition and the water-soluble polymers or gel forming polymers in Ortega are polyvinylpyrrolidone and cellulose derivatives such as hydroxypropylcellulose (column 3, lines 49-53). Example I prepares the composition by granulating theophylline and cellulose acetate

with polyvinylpyrrolidone in ethanol and the wet mass is dried and sieved. The theophylline based dried granules from the preceding step represents the at least one active agent of claim 1 b). The dried granulate is then mixed with a combination of polyvinylpyrrolidone, polyvinyl acetate and lubricant, which is made up of stearic acid, talc and magnesium stearate, to produce granules that are formulated into a final form of a tablet. The second step, where the dried theophylline particles and the PVP:PVA:lubricant are combined to produce granules of active theophylline composition does not use solvent and meets the process of claim 1. The molecular weight recited in claims 1, 4 and 17 is a broad range of 20,000 to 1,000,000 and this range is characteristic of the polyvinylpyrrolidone and polyvinyl acetate and since the prior art is silent on the molecular weight of the polyvinylpyrrolidone and polyvinyl acetate, it flows that polyvinylpyrrolidone and polyvinyl acetate having any molecular weight would work in the composition. Further, Example I describes particles having size less that 30 mesh, which is less than 595 μm; and this size lies within the particle size of 20-700 μm recited in claim 6. There is no demonstration in applicants' specification that shows that the particles size of 20-700 μm confers unusual results to the active agent. The disclosure of lubricant in the composition/formulation of Ortega meets the limitation of claim 7, the cellulose phthalate added in step 1 to produce the theophylline based dry granules meets the requirement of claim 12 where the excipient is added before, during or after granulation. Polyvinylpyrrolidone or the combination polyvinylpyrrolidone and polyvinyl acetate meet the water-soluble polymer requirement of claims 13, 16, 29. Fatty acids, salts of fatty acids, mineral oil and hydrogenated vegetable oils are also examples of lubricant that can be used in Ortega (column 3, lines 57-59) meeting claim 31 and 32. Also, hydroxypropyl methylcellulose, methylcellulose and sodium

carboxy methylcellulose are examples of water-soluble polymers that can be used in Ortega (column 3, lines 50-53) meeting claims 29, 30. However, Ortega, while teaching wet granulation for the first step in which the theophylline granules are made, Ortega does not specifically disclose the granulation process used in step 2 and specification does not disclose mixer granulation or fluidized bed granulation or extrusion granulation in either the first step of the second step. But these forms of granulation are known processes of granulation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to wet granulate the mixture of theophylline, polyvinylpyrrolidone, polyvinyl acetate, cellulose acetate phthalate and a mixture or stearic acid, magnesium stearate and talc according to Ortega. One having ordinary skill in the art would have been motivated to substitute one granulation process with another with the expectation of producing granules of the composition.

Response to Arguments

5. Applicant's arguments filed 5/11/06 have been fully considered but they are not persuasive.

Applicant argues that

a) Ortega's tablet contains PVP particles and PVA particles in compressed such that there is no indication that PVP is taken up by PVA particles to form particles encountered in the formulated PVP-PVA mixture and that "PVP and PVA are not miscible with one another ... so that simple combination , for example by a homogeneous melt, is not possible," so that wet granulation of PVP and PVA particles taught by Ortega does not result in the claimed composition. Thus, applicant argues that Ortega does not teach all the elements of the claims.

Response to a):

Ortega does not disclose homogeneously melting PVP and PVA. Ortega wet granulates theophylline and polyvinylpyrrolidone (PVP) and the theophylline-based product from the wet granulation step is dried in fluid bed granulator, see column 4, lines 32-34 (Example I). It is this dried theophylline based product that is combined with PVP and PVA and lubricant and the granules from this step are formulated into tablets. Therefore, Ortega does not wet granulate PVP and PVA. Therefore, Ortega discloses the process of claim 1 with respect to the process where 1 a) and 1 b) are granulated. Ortega does not indicate that solvent is used in the second step. The claim does not state any particular order of adding the components. Therefore, with respect to applicant's argument, Ortega discloses all the elements of the claims as described above. Furthermore claim 21 is a compressed tablet just as Ortega discloses compressed tablet.

6. Claims 1 and 8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ortega (US 4,837,032) in view of Noda et al. (US 5,389,380).

Ortega discloses the granulation of a composition that comprises theophylline, polyvinylpyrrolidone, polyvinyl acetate, cellulose acetate phthalate and lubricant, which is a mixture or stearic acid, magnesium stearate and talc. Ortega does not teach a theophylline composition that contains lactose, cellulose powder, mannitol, calcium diphosphate or starch as required by claim 8. Nonetheless, Noda discloses a theophylline composition comprising excipients such as lactose, sucrose, sorbitol and mannitol and higher fatty acid or polyethylene glycol (column 4, lines 43-47 and column 5, lines 63-65); and Noda is relied upon for a teaching of theophylline composition that contains lactose or starch or mannitol excipient. Therefore, it

would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising theophylline, polyvinylpyrrolidone, polyvinyl acetate, cellulose acetate phthalate and a mixture or stearic acid, magnesium stearate and talc. One having ordinary skill in the art would have been motivated to include excipients such as lactose, sucrose, sorbitol and mannitol and higher fatty acid or polyethylene glycol in the theophylline composition with the expectation of producing a sustained release formulation.

Response to Arguments

7. Applicants' arguments filed 5/11/06 have been fully considered but they are not persuasive.

Applicant argues that claims b) 1-9, 12, 13, 16-23, 25 and 27-33 cannot be rendered obvious by Ortega in view of Noda because Noda's disclosure "adds nothing to the teaching of Ortega" that could reasonably supplement or suggest motivation necessary to modify the tablet or the process as claimed, and the combination of Noda with Ortega is still deficient because the combined references do not teach all the limitations of the claims.

Response to b):

Claims 1 and 8 and not claims 1-9, 12, 13, 16-23, 25 and 27-33 are rejected as being unpatentable over Ortega in view of Noda. It is described above that Ortega discloses the claimed composition 1. The difference is that Ortega does not disclose the limitation of claim 8 and Noda was properly used as a secondary reference to show/demonstrate that theophylline based composition can be prepared using excipients such as lactose, sucrose, sorbitol and mannitol and higher fatty acid or polyethylene glycol (column 4, lines 43-47 and column 5, lines 63-65), the limitation of claim 8. The motivation to combine Noda with Ortega stems form the

disclosure that fatty acid and lactose, sucrose, sorbitol and mannitol are excipients that can be used in the formulation of theophylline based product. One excipient can be used in place of another excipient that are recognized as being equivalent in the art; the end result will be the production of sustained release theophylline composition. The reliance on Noda for teaching theophylline composition comprising excipients such as lactose, sucrose, sorbitol and mannitool and higher fatty acid or polyethylene glycol is proper since both references disclose theophylline.

No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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